510(k) Summary

Liquid Assayed Multiqual Premium

MAR 0 1 2013

K130162

1.0 **Submitter**

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Contact Person

Suzanne Parsons
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Date of Summary Preparation

February 26, 2013

2.0 **Device Identification**

Product Trade Name:	Liquid Assayed Multiqual Premium
Common Name:	Multi-Analyte Controls, All Kinds (Assayed)
Classifications:	Class I, Reserved
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

3.0 **Device to Which Substantial Equivalence is Claimed**

Predicate Device Information	
Device Name:	Liquid Assayed Multiqual
Applicant:	Bio-Rad Laboratories
510(k) Number:	K100727
Product Code:	JJY
Regulation #:	862.1660
Device Classification Name:	Multi-analyte Controls, All Kinds(Assayed)

4.0 Description of Device

This product is prepared from human serum to which purified biochemical material (tissue extracts of human and animal origin), chemicals, drugs, preservatives and stabilizers have been added. The control is provided in liquid form for convenience.

Table 1: Product Catalog Description

Description	Configuration
Liquid Assayed Multiqual Premium, Level 1	6 x 5 mL
Liquid Assayed Multiqual Premium, Level 2	6 x 5 mL
Liquid Assayed Multiqual Premium, Level 3	6 x 5 mL
Liquid Assayed Multiqual PremiumTrilevel MiniPak	3 x 5 mL (1 per level)

Each human donor unit used to manufacture this control was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2. This product may also contain other human source material for which there are no approved tests. In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

5.0 VALUE ASSIGNMENT

The mean values and the corresponding ±3SD ranges printed in this Insert were derived from replicate analyses and are specific for this lot of product. Data from Unity™ Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications.

The data printed in our package insert meet our internal processes and procedure requirements for the assignment of values.

6.0 Intended Use

Liquid Assayed Multiqual Premium is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

7.0 Comparison of the new device with the Predicate Device

Liquid Assayed Multiqual Premium is substantially equivalent to Liquid Assayed Multiqual currently in commercial distribution under 510(k) K100727. Table 1 (below) indicates similarities and differences between the new and predicate device.

Table 1. Similarities and Differences between new and predicate device.

	Liquid Assayed Multiqual Premium (New Device)		**Liquid Assayed Multiqual (Predicate Device – 510(k) cleared under K100727)**	
	Similarities			
Intended Use	Liquid Assayed Multiqual Premium is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.		Liquid Assayed Multiqual is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	
Matrix	Human Serum		Human Serum	
Form	Liquid		Liquid	
	Differences			
Analytes	**Contains:**		**Contains:**	
	Acetaminophen	Haptoglobin	Acetaminophen	Immunoglobulin M (IgM)
	Acid Phosphatase	Immunoglobulin A (IgA)	Alanine Aminotransferase (ALT/SGPT)	Iron
	Alanine Aminotransferase(ALT/SGPT)	Immunoglobulin G (IgG)	Albumin	Iron Binding Capacity, Total (TIBC)
	Albumin	Immunoglobulin M (IgM)	Alkaline Phosphatase (ALP)	Lactate (Lactic Acid)
	Alkaline Phosphatase (ALP)	Iron	Alpha-1-Antitrypsin	Lactate Dehydrogenase (LDH)
	Alpha-1-Acid Glycoprotein	Iron Binding Capacity, Total (TIBC)	Amylase	Lipase
	Alpha-1-Antitrypsin	Iron Binding Capacity, Unsaturated (UIBC)	Apolipoprotein A-1	Lithium
	Alpha-Hydroxybutyrate Dehydrogenase (aHBDH)	Kappa Light Chains	Apolipoprotein B	Magnesium
	Amikacin	Lactate (Lactic Acid)	Aspartate Aminotransferase (AST/SGOT)	Phenobarbital
	Amylase	Lactate Dehydrogenase (LDH)	Bilirubin, Direct	Phenytoin
	Amylase, Pancreatic	Lambda Light Chains	Bilirubin, Total	Phosphorus
	Anti-CCP	Lidocaine	C3 Complement	Potassium
	Apolipoprotein A-1	Lipase	C4 Complement	Prealbumin
	Apolipoprotein B	Lithium	Calcium, Total	Protein, Total
	ASO	Magnesium	Carbamazepine	Salicylate
	Aspartate Aminotransferase (AST/SGOT)	Methotrexate	Carbon Dioxide (CO2)	Sodium
	Beta-2-Microglobulin	NAPA	Ceruloplasmin	T3 Total
	Bile Acids	Osmolality	Chloride	T3 Uptake/T-Uptake
	Bilirubin, Direct	Phenobarbital	Cholesterol, High Density Lipoprotein (HDL)	T4 Free
	Bilirubin, Total	Phenytoin	Cholesterol, Low Density Lipoprotein (LDL)	T4 Total
	Bilirubin, Neonatal	Protein Electrophoresis	Cholesterol, Total	Theophylline
	C3 Complement	Phospholipids	Creatine Kinase (CK)	Thyroid Stimulating Hormone (TSH)
	C4 Complement	Phosphorus	Creatinine	Tobramycin
	Caffeine	Potassium	Digoxin	Transferrin
	Calcium, Ionized	Prealbumin	Ethanol	Triglycerides
	Calcium, Total	Procainamide	Ferritin	Urea Nitrogen (BUN)
	Carbamazepine	Protein, Total	Gamma Glutamyltransferase (GGT)	Uric Acid

	Carbon Dioxide (CO2)	Glucose	Gentamicin	Valproic Acid
	Ceruloplasmin	Quinidine	Glucose	Vitamin B12
	Chloride	Salicylate	Haptoglobin	Pseudocholinesterase
	Cholesterol, High Density Lipoprotein (HDL)	Sodium	Immunoglobulin A (IgA)	
	Cholesterol, Low Density Lipoprotein (LDL)	T3 Total	Immunoglobulin G (IgG)	
	Cholesterol, Total	T3 Uptake/T-Uptake		
	Cholinesterase	T4 Free	**Does not contain:**	
	Copper	T4 Total	Acid Phosphatase	Iron Binding Capacity, Unsaturated (UIBC)
	Cortisol	Theophylline	Alpha-1-Acid Glycoprotein	Kappa Light Chains
	Creatine Kinase (CK)	Thyroid Stimulating Hormone (TSH)	Alpha-Hydroxybutyrate Dehydrogenase (aHBDH)	Lambda Light Chains
	Creatinine	Tobramycin	Amikacin	Lidocaine
	CRP	Transferrin	Amylase, Pancreatic	Methotrexate
	Cystatin C	Triglycerides	Anti-CCP	NAPA
	Digoxin	Urea	ASO	Osmolality
	Disopyramide	Urea Nitrogen (BUN)	Beta-2-Microglobulin	Phospholipids
	Ethanol	Uric Acid	Bile Acids	Procainamide
	Ferritin	Valproic Acid	Bilirubin, Neonatal	Protein Electrophoresis
	Gamma Glutamyltransferase (GGT)	Vancomycin	Caffeine	Quinidine
	Gentamicin	Vitamin B12	Calcium, Ionized	Triglycerides
	Globulin	Zinc	CRP	Urea
	Does not contain:		Cystatin C	Uric Acid
	Pseudocholinesterase		Globulin	Vancomycin
Shelf Storage Stability	Until expiration date at -20 to -70 °C		Until expiration date at -20 to -50 °C	
Thawed & Unopened Vial Stability	When the control material is thawed and stored unopened at 2 to 8°C, all analytes will be stable for 30 days with the following exceptions: Direct Bilirubin will be stable for 11 days, Triglycerides, HDL, Cholinesterase, and Phosphorus will be stable for 7 days.		When this product is stored at 2 to 8°C unopened and the stopper is not punctured, all analytes will be stable for 30 days with the following exceptions: Direct Bilirubin will be stable for 11 days, Triglycerides, HDL, Pseudocholinesterase and Phosphorus will be stable for 7 days. This product can be used for 7 days when stored on-board the Siemens Dimension Vista at 2 to 8°C.	
Thawed and Opened Vial Stability	Once the control material is thawed and opened, all analytes will be stable for 14 days when stored tightly capped at 2 to 8°C, with the following exceptions: Direct Bilirubin, Triglycerides, HDL, Cholinesterase, and Phosphorus will be stable for 7 days.		Once the product stopper is punctured, all analytes will be stable for 5 days when stored at 2 to 8°C.	
Frozen Aliquot Stability	AST/SGOT, Direct Bilirubin, HDL, Phosphorus, LDL, and Triglycerides will be stable for 14 days when stored in tightly capped aliquot amber vials at -20 to -70°C.		No claims made.	
Fill Size	5 mL		2.5 mL	

8.0 Statement of Supporting Data

Real Time Stability studies were conducted to establish thawed (opened and unopened vial) stability and frozen aliquot stability claims. Accelerated Stability studies were conducted to establish the shelf life stability claims. Acceptance criteria were met to support product as claimed:

Thawed and Opened Vial Stability: All analytes will be stable for 14 days when stored tightly capped at 2 to 8°C, with the following exceptions: Direct Bilirubin, Triglycerides, HDL,

Cholinesterase, and Phosphorus will be stable for 7 days.

Thawed and Unopened Vial Stability: All analytes will be stable for 14 days when stored tightly capped at 2 to 8°C, with the following exceptions: Direct Bilirubin, Triglycerides, HDL, Cholinesterase, and Phosphorus will be stable for 7 days.

Frozen Aliquot Stability: AST/SGOT, Direct Bilirubin, HDL, Phosphorus, LDL, and Triglycerides will be stable for 14 days when stored in tightly capped aliquot amber vials at -20 to -70°C.

Shelf life Stability: 3 Years at -20 to -70 °C

9.0 Conclusion

Based on the performance characteristics indicated above, Liquid Assayed Multiqual Premium Control is substantially equivalent to the predicate device.

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

March 1, 2013

Bio-Rad Laboratories
c/o Suzanne Parsons
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: k130162
Trade/Device Name: Liquid Assayed Multiqual Premium
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material
Regulatory Class: Class I, Reserved
Product Code: JJY
Dated: January 21, 2013
Received: January 23, 2013

Dear Ms. Suzanne Parsons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k130162

Device Name: **Liquid Assayed Multiqual Premium**

Indications for Use:

Liquid Assayed Multiqual Premium is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

Prescription Use X And/Or Over the Counter Use ___.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k130162